

ON-SITE ASSESSMENT
APPENDIX A

NELAC BASIC ASSESSOR TRAINING
STANDARD

PROPOSED CHANGES

Appendix A - NELAC BASIC ASSESSOR TRAINING

A.1 Introduction

Appendix A specifies the minimum standards for NELAC Basic Assessor Training Courses. This appendix must be used by training providers to design basic training courses for laboratory assessors. It can also be used by accrediting authorities to evaluate the acceptability of existing basic training courses, and by assessors to gain familiarity with the content of such courses. Appendix A and its technical counterpart, Appendix B, specify the principal elements of NELAC laboratory assessor training courses.

A.2 Course Purpose

The purpose of the NELAC Basic Assessor Training Course is to fulfill the Basic Training requirement for assessors specified in Section 3.1 of the NELAC Standards.

The Basic Assessor Training Course:

- Instructs assessors on the basic elements of performing NELAC assessments by focusing on evaluating laboratory quality systems.
- Provides an overview of the NELAC Standards and the NELAP laboratory accreditation process.
- Promotes uniformity of laboratory assessments performed to obtain NELAP accreditation.
- Facilitates information exchange among assessors.

A.3 Course Logistics

The course subject matter and content must be organized in modules or discrete units. Although the order of instructional modules or units is not strictly prescribed, courses must be organized systematically and logically to allow the best assimilation and comprehension of their subject matter.

The course contents can be delivered in a traditional classroom, by teleconferencing, in computer on-line sessions, or by a combination of any of these media. The format for instruction modules or units must be appropriate to the subject matter and can include, but is not limited to, lectures, discussions, demonstrations, critiques, group exercises, written assignments, simulations, fictitious reenactments, or a combination of any of these. Regardless of the medium or format used for content delivery, all courses must provide opportunity for ample interaction between instructors and participants and, must include exercises designed to be completed by teams of participants.

A.3.1 Duration

The duration of the course will depend upon the participants' experience and the course's mode of delivery, but must be sufficient to allow fulfilling all the objectives contained in section A.2 and to cover the content specified in section A.4. Typical Basic Assessor Training courses will dedicate a minimum of 36 hours or four and a half days to accomplish this.

A.3.2 Providers, Instructors, and Participants

Providers of NELAC Basic Assessor Training Courses shall ensure that the number of instructors assigned to a course is commensurate with the number of participants attending and the delivery mode of the course. Although other ratios of instructor to students may be acceptable, a typical Basic Assessor Training Course delivered in a traditional classroom setting assigns one instructor per every 15 participants.

Instructors must maintain credentials and qualification statements and must make them available to course participants or other interested parties.

Only accrediting authorities can approve training programs for their assessors. Providers of NELAC Basic Training Courses shall not claim NELAP approval of them and are restricted from using the NELAC and NELAP logos in any course or promotional materials.

This Appendix does not limit course participants to those employed by accrediting authorities. All participants, regardless of the course delivery mode, must register prior to taking a course. Providers must maintain records that identify participating students and their status (i.e. whether they have attended the course or completed one by passing an examination); however, it is the responsibility of accrediting authorities to qualify and approve their assessors.

Providers must update established courses and existing training materials to reflect any changes in effect made to the NELAC standards.

A.3.3 Course Documentation Supplied to Participants, Final Examination, and Certificates

After receiving completed registration forms including fees (where charged), providers shall send participants a course agenda. The course agenda should contain titles of the instructional modules and units with a timetable, and should be sent to candidates in sufficient time to be read before the course. Providers must also provide with the agenda a copy of the NELAC Standards and the Quality System Checklist in effect at the time the course.

Providers may make available to participants other documents such as checklists, forms, guides, case studies, summaries, flowcharts, and tabulations to enhance or supplement course instruction. However, these materials must not be used to re-interpret the NELAC standards or in lieu of them. Providers must not misconstrue any such supplemental materials as being required or containing requirements in addition to those currently in the NELAC standards. Supplemental documents need not be provided to participants prior to the course.

A.3.4 Final Examination

Participants must be offered an opportunity to take a written examination that quantitatively measures their knowledge of the NELAC standards and the course contents. Until such time as NELAP or a designated body can maintain a controlled set of questions to be used in written examinations, providers shall design their own questions and grading criteria. Participants that obtain 70% or more correct answers in the final examination are classified as successfully completing the course.

A.3.6 Attendance or Completion Certificate

Course providers shall issue certificates to those participants who attend all the offered modules or instructional units and to those that successfully complete the course. A "Certificate of Attendance" containing a brief description of the course shall be issued to participants who choose not to take the final examination or who do not successfully complete the course, but who have attended all the modules or instructional units.

Participants that attend all the instruction modules and who successfully complete the course shall be issued a "Certificate of Completion".

A.3.6 Appraisal of Course by Participants

Participants shall be offered an evaluation form at the end of the course to invite feedback to providers about the course's quality and content. Such forms shall be available to accrediting authorities and to NELAP upon request.

Providers are also encouraged to include in their courses an open session where participants evaluate a course and offer direct feedback to instructors.

A.4 Course Contents

The contents of the Basic Assessor Training Course must address the following items.

A.4.1 Introduction

The purpose of this module is to establish the intent and tone of the course. It should create an atmosphere that will encourage participation, feedback, and questions, and should clarify participant expectations about the intent and content of the course.

This module should provide an opportunity to:

1. Welcome participants
2. Introduce course content
3. Describe method of assessment of participants
4. Describe administrative and physical arrangements (e.g. lunches, telephone, timing)
5. Have participants introduce themselves

A.4.2 Historical Perspective on National Accreditation

This course module will provide a background on laboratory accreditation and the history included Chapter 1 of the NELAC standard. The historical perspective and overview of the requirements of assessors should enable participants to understand the benefits of national accreditation and how a uniform national accreditation process will improve the quality of environmental data.

1. The Need for National Accreditation
2. Past Efforts toward National Consistency
3. Genesis of the National Environmental Laboratory Accreditation Program (NELAP)

A.4.3 Fundamentals of NELAC and NELAP

The purpose of this module is to familiarize the course participants with the function and structure of NELAC, NELAP, and the essential role that the accrediting authorities have in the laboratory accreditation process. The module should establish for each participant a working knowledge of NELAC and the mechanics of the program.

What is NELAC

1. Objectives of NELAC
2. Structure and Operation of NELAC
 - a. NELAC Standards
3. What is NELAP
 - a. Current Status of NELAP
4. Structure and Operation of NELAP
5. Primary Accrediting Authorities
 - a. Requirements and Functions of Primary Accrediting Authorities
 - b. Process for Recognition of Accrediting Authorities
6. Secondary Accrediting Authorities
 - a. Requirements and Functions of Secondary Accrediting Authorities
 - b. Reciprocal Accreditation
7. National Accreditation Database

A.4.4 Qualifications and Training Requirements for Assessors

The purpose of this module is to examine the requirements for becoming a qualified NELAC Assessor as defined in Chapter 3. At the end of the session each participant should understand the process and timing involved for becoming a NELAC assessor.

1. Basic Qualifications
 - a. Qualification by an Accrediting Authority
 - b. Absence of Conflict of Interest Certification
2. Purpose of Training Assessors
3. Basic Assessor Training
4. Technical Training
5. Refresher Training

A.4.5 Accreditation of Laboratories

The purpose of this module is to define the NELAC laboratory accreditation process. Participants should understand the requirements of laboratories seeking accreditation and the process through which accreditation is granted.

1. Accreditation Requirements
2. Accreditation Process
 - a. Order of the Accreditation Process
 - b. Role of the Laboratory Assessor in Accreditation of Laboratories

A.4.6 Proficiency Testing

The purpose of this module is to provide a comprehensive view of the role that the proficiency testing (PT) plays in the accreditation process. Participants should understand the importance of proficiency testing, the requirements for PT providers and laboratories, and the elements of the PT process that should be assessed during the on-site assessment.

1. Purpose of Proficiency Testing
2. Definitions
3. Mechanisms, Criteria, Current Programs, Follow-Up Actions
4. Oversight and Delivery of Proficiency Testing Program
 - a. Proficiency Testing Providers
 - b. Proficiency Testing Oversight Body
 - c. Primary Accrediting Authorities
5. Laboratory Requirements
 - a. Types of PT Samples Required to be Analyzed
 - i. PT Fields of Testing
 - b. Frequency of PT Sample Analyses
 - c. Requirements for Handling and Analyzing PT Samples
6. Role of the Laboratory Assessor in Reviewing PT Sample Data

A.4.7 Ethical Conduct Standards for Assessors

This module will review the elements of ethical conduct of assessors, establishing an expectation that assessor conduct be "above reproach," and the consequences of unethical conduct. In addition, the module will examine circumstances when an assessor activity might constitute a potential conflict of interest, and the need for disclosure. At the end of this session, participants should know the NELAC expectations and requirements for assessor conduct.

1. Professional Conduct of Assessors
2. Defining, Determining, and Avoiding Conflicts of Interest for Assessors

A.4.8 Quality Systems

This module establishes the fundamental components of a quality system and trains assessors on how to evaluate them. It requires a group exercise in which a laboratory's quality manual is evaluated for conformance with the NELAC Standards. This case study can be used to emphasize the importance of key quality system elements.

1. Definition of a Quality System
 - a. Quality Assurance
 - b. Quality Control
 - c. Elements of a Quality System
2. Quality System Requirements for Laboratories
 - a. Quality Manual
 - b. Quality Assurance Policies and Procedures
 - c. Standard Operating Procedures

- d. Corrective Actions
- e. Document and Records Control
- f. Data Review and Evaluation
- 3. Monitoring Effectiveness of the Quality System
 - a. Internal Audits
 - b. Management Review

A.4.9 NELAC Quality System Checklist

This module will explore the proper use of the Quality Systems Checklist, including how and when the checklist should be completed, and the techniques that a good assessor follows when using any checklist. At the end of this module, participants should be familiar with the Quality Systems Checklist and how it relates to NELAC Chapter 5. Participants will learn how to use the Quality Systems Checklist as an assessment tool, rather than as the primary vehicle of the assessment.

- 1. Purpose
- 2. Mandatory Use
- 3. Use of the Quality System Checklist Before, During, and After Laboratory Assessments

A.4.10 Interviewing Techniques for Assessors

The purpose of this module is to instruct participants on good interviewing techniques and the personal dynamics of an On-Site Assessment. Participants will learn communication skills, including effective questioning techniques; methods for gathering information in an objective and professional manner; and potential ethical concerns. Group exercises and simulations are particularly effective in this sub-unit.

- 1. Utility of Interviews During Laboratory Assessments
- 2. Interview Structure
- 3. Verbal and Non-Verbal Communication
- 4. Modes of Gathering Information
- 5. Ways of Asking Questions
- 6. Dealing with Difficult Interviewees

A.4.11 NELAC Laboratory Assessments

This module of the course presents all phases of the assessment process: pre-assessment, on-site assessment, and post-assessment activities. The session should instruct participants in the use of assessment tools (e.g., observation, interviewing, documentation review, and tracking) to review the quality system, documented test procedures, test method validation, and the technical competence of a laboratory.

- 1. Purpose of Assessments
- 2. Frequency and Types of Assessments
- 3. Phases of an Assessment

A.4.11. 1 Pre-Assessment Activities

- 1. Planning an Assessment

- a. Scope of an Assessment
 - b. Appointment of Lead Assessor and other Team Members
 - c. Roles of Assessment Team Member
2. Document Review
 - a. PT Sample Results
 - b. Quality Manual
 - c. Corrective Action Reports and Plans
3. Previous Assessment Reports
4. Preparation of Agenda and Schedule
5. Notifications

A.4.11.2 On-Site Assessment Components

A "mock" assessment exercise can be used during this sub-unit to instruct participants on the components of On-Site assessments.

A.4.11. 2.1 Opening Conference

1. Schedule and Agenda
2. Assessment Appraisal Form
3. Confidential Business Information (CBI)

A.4.11. 2.2 Facility Walk-Through

A.4.11. 2.3 On-Site Assessment Proper

1. Use of the Quality Systems Checklist
2. Detailed Tour and Observation of Operations
3. Staff Interviews
4. Calibration and Traceability of Measurements
 - a. Uncertainty of Measurements
5. Data and Document Review

A.4.11. 2. 4. Assessment Team Meetings

A.4.11.2.5 Closing Conference

1. Reporting Non-Conformances

A.4.11.3 Post On-Site Assessment Activities

During this sub-unit participants should be instructed on how to correctly cite instances of non-conformance in assessment reports as well as effective ways of formatting them. Critiques of fictitious reports, or a writing assignment in which participants write a report of a "mock" assessment are particularly effective in this sub-unit.

1. On-Site Assessment Report
2. Report Format

3. Report Release
4. Corrective Action Reports in Response to On-Site Assessment
5. Surveillance and Re-Assessment.
6. Retention of Assessment Documents

A.4.12 Handling Assessment Challenges

The purpose of this sub-unit is to identify effective methods of handling potential problems during an assessment. Participants should gain useful conflict resolution tools during this session. Group exercises and simulations can be used effectively in this sub-unit.

1. Dealing with Improper Practices and Potentially Illegal Activities
2. Dealing with Unexpected Circumstances
3. Technical Disagreements
4. Absence of Key Laboratory Personnel
5. Hostile Reception
6. Conduct of Assessors During On-Site Assessments

A.5.0 Performance Based Measurement System (PBMS)

The purpose of this module is to present an overview of PBMS and EPA's commitment to implementing PBMS. The module will summarize the status of PBMS implementation, potential difficulties, and how methods based on a PBMS should be assessed. Participants should leave the session with an understanding of what PBMS is and how PBMS methods can be assessed.

1. Definition
2. Relationship of NELAC Standard to PBMS.
3. Assessing Laboratories that Use PBMS.

A.6. 0 Course Summary and Conclusions

This module should conclude the instructional components of the course. It should present a course review that gives a global perspective of the purpose of NELAC and the laboratory assessment process. Participants should be given an opportunity to ask final questions about specific aspects of the assessment and accreditation process at this time.

A.7. 0 Final Examination

The last module of the course is the final examination. The examination determines whether a participant has sufficient knowledge of the NELAC Standards and effective assessment procedures to be a NELAC assessor.

A.8 REFERENCES

1. ILAC-G3: 1994, "Guidelines for Training Courses for Assessors Used by Laboratory Accreditation Schemes"